



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M2832m
Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

August 2, 1999

Cin WL 99-342

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Daniel E. Stump, M.D.
Chairman, Department of Radiology
Wooster Community Hospital
Breast Health Center
1761 Beall Ave.
Wooster, OH 44691

Facility I.D.#:157024

Dear Dr. Stump:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on July 7, 1999. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Your records lack the required information that the following interpreting physicians, [REDACTED] and [REDACTED] are qualified to interpret mammograms. Your records did not demonstrate that [REDACTED] have either board certification from any of the approved boards or two months full-time training in the interpretation of mammograms.

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. There were inadequate records regarding the initial training of 40 hours of continuing medical education in mammography for each of the following interpreting physicians:
[REDACTED]

2. There were inadequate records regarding the interpreting physicians' initial experience reading and interpreting mammograms of at least 240 patients in 6 months for each of the following interpreting physicians: [REDACTED]

3. There were inadequate records that the interpreting physicians, [REDACTED] meets the continuing experience requirement in reading and interpreting 960 patient mammograms in a 24 month period preceding the current inspection.

The other items listed in your July 7, 1999 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address these Level 3 items in your written response.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

On July 26, 1999, this office received a letter dated July 20, 1999 from you. This letter addressed the noncompliance issues that were observed by Ms. Terri Eckert on July 7, 1999.

Unfortunately, your letter did not cover the following deficiencies:

- 1. Your records lack the required information that the following interpreting physicians, [REDACTED] and [REDACTED] are qualified to interpret mammograms. Your records did not demonstrate that [REDACTED] have either board certification from any of the approved boards or two months full-time training in the interpretation of mammograms.

Your letter included a very poor copy of the residency letter regarding [REDACTED]. Also, [REDACTED] residency letter did not address specific topics covering the minimum of 2 month training received in the residency. Please note that two months of training is equivalent to 280 hours of formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics specific to mammography, radiation effects and radiation protection.

In the case of [REDACTED], you submitted documentation regarding [REDACTED] certification status with the American Board of Radiology. Unfortunately, these are not acceptable because [REDACTED] did not pass the oral examination. You also submitted [REDACTED] attestation statement dated June 1, 1996. This attestation statement is not acceptable. It is the policy of the Food and Drug Administration, that the documentation demonstrating two month of training must be on a letterhead or a certificate from the organization(s) that provided the required two months of training. You also submitted [REDACTED] residency certificates from [REDACTED], dated September 30, 1991 and [REDACTED], dated November 13, 1980. These documents do not state specifically the topics covering the minimum of 2 months training as mentioned above paragraph regarding [REDACTED] case.

- 2. There were inadequate records demonstrating that [REDACTED] received initial training of forty (40) hours of continuing education in mammography; initial experience of reading and interpreting mammograms of at least 240 patients in 6 months.

Your letter included the attestation statements dated, July 12, 1999, July 7, 1999 and June 22, 1996 signed by [REDACTED] respectively, These attestation statements do not addressed the specific time and location(s) that these radiologists received their mammography training prior to October 1, 1994. Also these attestation statements do not addressed the specific location(s) that these radiologists performed the readings of 240 mammograms in a six month period prior to October 1, 1994.

Your July 20, 1999, letter adequately covered noncompliance issue regarding the [REDACTED] continuing experience requirement of reading 960 patient mammograms in a two year period.

If you are having difficulty obtaining the proper documentation from the above-mentioned radiologists, you could consider having the mammograms that were originally read by the above-mentioned radiologists to be double read by an MQSA qualified radiologist(s).

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

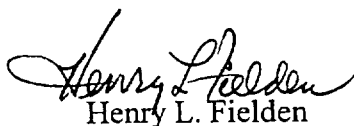
R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Terri Eckert
Ohio Department of Health
Northeast District Office
Oliver R. Ocasek Government Office Building
161 S. High St., Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513)679-2700, extension 138.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Henry L. Fielden".

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/TEckert